UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

LATONIA CRAWFORD, **Plaintiff** **v.** **ZIMMER BIOMET HOLDINGS, INC., et al.,** **Defendants**	**CASE NO. 1:21-CV-0988 AWI CDB** **ORDER ON DEFENDANTS' MOTION TO DISMISS** (Doc. Nos. 34, 36)

This is a products liability case brought by Plaintiff Latonia Crawford against Zimmer Biomet Holdings, Inc., Zimmer Biomet, Inc., and Zimmer Biomet U.S., Inc. (collectively "Zimmer"). In the operative First Amended Complaint ("FAC"), Plaintiff alleges state law claims based on strict products liability, negligence, misrepresentation, and breach of implied and express warranties in connection with a hip replacement. Currently before the Court is Zimmer's Rule 12(b)(6) motion to dismiss and, in the alternative, Rule 12(f) motion to strike. For the reasons that follow, the motion to dismiss will be granted in part and denied in part, and the motion to strike will be denied.

RULE 12(b)(6) FRAMEWORK

Under Federal Rule of Civil Procedure 12(b)(6), a claim may be dismissed because of the plaintiff's "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). A dismissal under Rule 12(b)(6) may be based on the lack of a cognizable legal theory or on the absence of sufficient facts alleged under a cognizable legal theory. See Yoshikawa v. Seguirant,

41 F.4th 1109, 1114 (9th Cir. 2022). In reviewing a complaint under Rule 12(b)(6), all well-pleaded allegations of material fact are taken as true and construed in the light most favorable to the non-moving party. Benavidez v. County of San Diego, 993 F.3d 1134, 1144 (9th Cir. 2021). However, complaints that offer no more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Benavidez, 993 F.3d at 1145. The Court is "not required to accept as true allegations that contradict exhibits attached to the Complaint or matters properly subject to judicial notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." Seven Arts Filmed Entm't, Ltd. v. Content Media Corp. PLC, 733 F.3d 1251, 1254 (9th Cir. 2013). To avoid a Rule 12(b)(6) dismissal, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 678; Armstrong v. Reynolds, 22 F.4th 1058, 1070 (9th Cir. 2022). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678; Miller v. Sawant, 18 F.4th 328, 336 (9th Cir. 2022). Plaintiffs cannot "rely on anticipated discovery to satisfy Rules 8 and 12(b)(6); rather, pleadings must assert well-pleaded factual allegations to advance to discovery." Whitaker v. Tesla Motors, Inc., 985 F.3d 1173, 1177 (9th Cir. 2021); see Mujica v. AirScan, Inc., 771 F.3d 580, 593 (9th Cir. 2014). If a motion to dismiss is granted, "[the] district court should grant leave to amend even if no request to amend the pleading was made . . . ." Ebner v. Fresh, Inc., 838 F.3d 958, 962 (9th Cir. 2016). However, leave to amend need not be granted if amendment would be futile or the plaintiff has failed to cure deficiencies despite repeated opportunities. Garmon v. County of L.A., 828 F.3d 837, 842 (9th Cir. 2016).

FACTUAL BACKGROUND

From the FAC, on November 11, 2014, Crawford underwent a left hip replacement with implants manufactured by Zimmer. The hip replacement involved implanting at least five components to form a new hip joint: a taberlock femoral (made of titanium alloy), a femoral head (made of a cobalt-chromium alloy), a low profile self-tapping bone screw, an acetabular liner

(made of antioxidant infused polyethylene), and a 2-hole shell (made of a titanium alloy). These components are collectively referred to as the Hip System.[1] However, between November 11, 2014 and December 26, 2014, Crawford suffered dislocations in the left hip/Hip System. After various resets, it was determined that another surgery was needed to secure the left hip.

On December 26, 2014, Crawford had an open reduction and revision of the acetabular component in response to dislocations. During this surgery, at least three components were implanted: an acetabular lock ring (made of titanium), an acetabular liner (made of antioxidant infused polyethylene), and new femoral head (made of a cobalt-chromium alloy). During the surgical procedure, it was determined that the acetabular lock ring had displaced, the acetabular liner was too low and had to be rebuilt, and the femoral head was scuffed from prior dislocations and had to be replaced.

In early 2015, Crawford's artificial hip again dislocated. The acetabulum was inspected and it was determined that the acetabular liner was fractured in multiple places. To correct the situation, Crawford underwent a surgical procedure to replace the acetabular liner. On February 24, 2015, the following components were implanted: a lock ring (made of titanium), a constrained liner (made of polyethylene and a titanium alloy constraint ring), and a modular head (made of a cobalt-chromium alloy). During this surgery, it was determined that pieces of the fractured polyethylene acetabular liner were within the acetabulum and that the ring lock mechanism had failed.

On November 23, 2019, Crawford had corrective surgery on her left hip. During the course of the surgery, it was discovered that: the Hip System had a broken metal head, the acetabular cup had broken; Crawford was suffering from metallosis (a type of metal poisoning that can occur when metal components of artificial joints fret/rub against each other and release microscopic metal particles into the blood and surrounding tissue; Crawford had pseudotumor

[1] At various points throughout the FAC, there is a reference to Zimmer's "Hip System." However, the FAC does not expressly define what is meant by the "Hip System." Considering that a natural hip has different parts or components, it is logical to assume that an artificial hip would also contain different parts or components, all of which come together to form a single functioning hip. Therefore, the Court will view all implanted components that were used to form a single functioning hip as "the Hip System."

formation round the hip and pelvis; the constrained liner was broken due to mechanical impingement with flexion; and the ring of the constrained liner was broken.

After the 2019 surgery, and in discussions with her surgeon, Crawford discovered that the Zimmer implants had failed. The failure resulted in multiple dislocations, repair surgeries, and metallosis (which is a chronic lifelong condition). Crawford never acted in a manner that contributed to the harms caused by Zimmer's implants.

The Zimmer implants used on Crawford had dissimilar metals, including titanium and cobalt-chromium alloys. The acetabular liners that failed were made of polyethylenes. Before designing the Hip System, Zimmer knew of the danger of cobalt-chromium metal debris if such debris were released into the body through fretting, corrosion, and micromotion. The Hip System has threading on the taper, and the threading has shallow grooves. The threading on the taper is for the use of a ceramic head. The taper threading protects ceramic heads and provides an interface at the junction with a metal head. However, the use of metal heads are much more likely to wear and produce debris from fretting. The threads were not designed to enhance the performance of metal heads. Zimmer's decision to allow the use of metals and cobalt-chromium heads instead of ceramic heads created an unreasonable risk and made the Hip System defective. The concept that corrosion might occur at the head-neck taper junction of a total hip prosthesis was first described in the early 1980's. Zimmer knew that the use of dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and flexural rigidity contribute to causing fretting and corrosion at the femoral head-neck/stem taper interface. Further, mechanically assisted crevice corrosion has been identified as a cause for symptomatic implant failure in metal-on-polyethylene hips. Mechanically assisted crevice corrosion produces cobalt and chromium ions and corrosive debris that can lead to adverse local tissue reaction.

Zimmer marketed its Hip System to surgeons and hospitals instead of end users like Crawford. The mechanical environment of the Hip System's junction creates an increased risk for failure due to pain, swelling, pseudotumor formation, metallosis, tissue reaction, synovitis, osteolysis, and dislocation resulting from excessive wear debris, fretting, corrosion, and recurrent repassivation. Each interface introduces a contributing source for metal wear and debris

generation. Each junction exponentially compounds and accelerates the wear debris generation process. Corrosion is time sensitive and accelerated with mechanical stresses. This phenomenon was known to Zimmer, or should have been known to Zimmer, at all relevant times. Zimmer also knew or should have known that the combination of metal alloys at a junction (such as the metal cobalt-chromium heads, cobalt-chromium neck/stem junctions, and/or titanium neck/stem junctions) for the Hip System generate excessive fretting, corrosion, and metal wear debris. However, Zimmer does not inform physicians or consumers that selection of a metal cobalt-chromium head instead of a ceramic head to pair with either a cobalt-chromium or titanium neck/stem significantly increases the risk of toxic amounts of corrosion and metal debris, which in turn can cause pain, swelling, metallosis, trunnionosis, tissue necrosis, tissue reaction, osteolysis, dislocation, and/or the need for early revision surgery. Zimmer also did not inform physicians about its inadequate testing procedures with respect to its Hip System. Zimmer gave reassurances of product safety through promotional materials, direct promotional contact, and/or word of mouth. Despite the reassurances, the Hip System when used with a cobalt-chromium head generates excessive fretting and corrosion at the head-neck/stem taper junctions. The fretting and corrosion generates toxic metal debris, metal ions, and other chemical byproducts which are released into the surrounding tissue. This often causes pseudotumors and other related conditions. Zimmer was aware of these problems at all relevant times.

DEFENDANTS' MOTION

Defendants' Arguments

Zimmer argues that no plausible claims are stated in the FAC.

With respect to the strict liability design defect, Zimmer argues that, under California law, a manufacturer of implantable medical devices cannot be held liable under such a theory. Therefore, this claim should be dismissed without leave to amend.

With respect to the strict liability failure to warn claim, Zimmer argues that the duty to warn runs to the physician/surgeon, and that the allegations must show that the physician would have acted differently if a different warning had been given. However, the FAC contains no

allegations regarding a warning directed to her treating physician (rather the allegations involve the medical community as a whole) and thus, fails to establish any duty by Zimmer to issue different warnings. Therefore, no plausible claim is stated and the claim should be dismissed.

With respect to the strict liability manufacturing defect claim, the FAC makes only conclusory allegations and fails to identify how the Hip System deviated from Zimmer's intended design. Therefore, no plausible claim is stated and the claim should be dismissed.

With respect to the negligence claim, the FAC alleges that each of the three strict liability claims are also negligence claims. However, for the same reasons that the strict liability claims fail, the negligence claim fails as well. Additionally, no plausible design defect claim is stated because the allegations are cut and pasted from a case filed in the Middle District of North Carolina that involve a product different from the Hip System. Further, the allegations do not adequately establish causation. Therefore, no plausible claim is stated and the claim should be dismissed.

With respect to the negligent misrepresentation claim, this claim sounds in fraud. The FAC fails to meet the Rule 9(b) pleading standards for fraud based claims because the who, what, when, where, and how of the misrepresentation is not alleged. Therefore, no plausible claim is stated and the claim should be dismissed.

With respect to the breach of implied and express warranty claims, these claims require the existence contractual privity. However, there is no privity. The FAC does not allege that Crawford purchased the Hip System from Zimmer, but does show that Crawford relied on her physician to select the Hip System.

Finally, Zimmer argues that almost all of the FAC should be stricken under Rule 12(f) because the allegations have been improperly cribbed/copied from a case filed in the Middle District of North Carolina. That case involved a different product that was manufactured by a different manufacturer. Cribbing allegations from an unrelated case is improper and does not actually result in allegations that are relevant, pertinent, and true with respect to the facts of Crawford's case. The practice does not provide Zimmer with adequate notice, is improper, and implicates the protections and prohibitions of Rule 11.

Plaintiff's Opposition

Crawford argues that she has pled plausible claims to the extent that she is able to and based on the facts she has available to her at this time.

With respect to the strict liability design defect claim, Crawford argues that because the FAC alleges that Zimmer was aware of the dangers of its design, failed to mitigate those dangers, and placed the defectively designed Hip System into the stream of commerce, a strict liability design defect claim is stated.

With respect to the strict liability failure to warn claim, Crawford argues that the FAC alleges that Zimmer failed to warn health care professionals including Crawford's physician of the danger of corrosion, micromotion, and fretting causing micro metal debris from the Hip System. Because a failure to warn Crawford's physician is alleged, dismissal is not appropriate.

With respect to strict liability manufacturing defect, Crawford argues that she has alleged the Hip System failed and resulted in *inter alia* metallosis. Crawford alleges that she is unsure what led to the failure and metallosis, but that the information should come once her two implanting surgeons are deposed. Until the depositions occur, Crawford alleges that she has pled all she can and that her allegations are sufficient. Thus, dismissal is not appropriate.

With respect to the negligence claims, Crawford alleges that she has pled all she can at this point and can provide more detail following discovery. Nevertheless, because plausible claims are alleged, dismissal is inappropriate.

With respect to the negligent misrepresentation claim, Crawford argues that this claim does not sound in fraud. Because the claim does not sound in fraud, the FAC does not need to comply with Rule 9(b).

With respect to the implied warranty claim, Crawford argues that Zimmer has overlooked California law that excuses the privity requirement with respect to pharmaceuticals/prescription drugs. This exception should apply to the Hip System. Because the privity requirement is excused, dismissal is inappropriate.

With respect to the express warranty claim, the FAC alleges that the warranty is based on labels and written advertising materials. California courts recognize that the privity requirement

on an express warranty claim is excused when the warranty claim is based on representations found in labels and written advertising materials. Therefore, dismissal is inappropriate.

Discussion

1. First Cause of Action – Strict Products Liability – Design Defect

California courts have held that manufacturers of medical implants that are available only by resort to the services of a physician are immune from a strictly liability design defect theory. See Zetz v. Boston Scientific Corp., 398 F.Supp.3d 700, 709 (E.D. Cal. 2019); Garrett v. Howmedica Osteonics Corp., 214 Cal.App.4th 173, 184 (2013); Artiglio v. Superior Ct., 22 Cal.App.4th 1388, 1397 (1994); Huft v. Horowitz, 4 Cal.App.4th 8, 18 (1992). Therefore, Crawford's strict liability design defect claim will be dismissed. See id.

2. Second Cause of Action – Strict Products Liability – Failure to Warn

Manufacturers are strictly liable for injuries caused by their failure to provide adequate warnings of known or reasonably scientifically knowable dangers at the time they manufactured and distributed their products. Johnson v. American Standard, Inc., 43 Cal.4th 56, 64 (2008); Carlin v. Superior Ct., 13 Cal.4th 1104, 1108-09, 1112 (1996). In the context of prescription drugs and medical implants, California has adopted the "learned intermediary" doctrine. See Webb v. Special Electric Co., Inc., 63 Cal.4th 167, 187 n.10 (2016); Amiodarone Cases, 84 Cal.App.5th 1091, 1103-04 (2022); Bigler-Engler v. Breg, Inc., 7 Cal.App.5t h 276, 319 (2017); Valentine v. Baxter Healthcare Corp., 68 Cal.App.4t h 1467, 1483 (1999). Under the "learned intermediary" doctrine, the physician who prescribes a medication or medical implant stands in the shoes of the consumer/patient and thus, the duty to warn runs to the physician, not the patient. See Bigler-Engler, 7 Cal.App.5t h at 319; Valentine, 68 Cal.App.4th at 1483. That is, "manufacturers have a duty warn physicians of risks that are known or scientifically knowable at the time of the [prescription drug's or medical implant's] distribution." Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227, 1238 (9th Cir. 2017).

A plausible claim for a failure to warn should include allegations that *inter alia* identify which danger was not warned against, explain that the danger was substantial, and that the danger was known or reasonably knowable, or explain how any warning that was given was inadequate.

Marroquin v. Pfizer, Inc., 367 F.Supp.3d 1152, 1161 (E.D. Cal. 2019). Further, because the failure to warn must be a substantial factor in causing the plaintiff's harm, see Ramos v. Brenntag Specialties, Inc., 63 Cal.4th 500, 509 (2016), a plaintiff must show that the prescribing physician's conduct would have changed if an adequate warning had been given. See Wendell, 858 F.3d at 1238; Andren v. Alere, Inc., 207 F.Supp.3d 1133, 1144 (S.D. Cal. 2016). "If adequate warning of potential dangers of a drug [or medical implant] has been given to doctors, there is no need by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed." Stevens v. Parke, Davis & Co, 9 Cal.3d 51, 65 (1973); Bigler-Engler, 7 Cal.App.5th at 319. Further, manufacturers generally are not required to provide a warning about a risk that is readily known and apparent to the medical community. See Carlin, 13 Cal.4th at 1116; Plenger v. Alza Corp., 11 Cal.App.4th 349, 362 (1992). "Whether the warning is adequate is usually a question of fact." Schwoerer v. Union Oil Co., 14 Cal.App.4th 103, 112 (1993).

Here, the second cause of action contains a number of allegations that are unnecessary and irrelevant to a plausible strict liability failure to warn claim.[2] Nevertheless, the Court is satisfied that there is a plausible claim contained within the second cause of action. The FAC alleges that Zimmer's Hip System "contained an absence of warnings alerting the medical community . . . to the dangerous risks associated with the Hip System," including: "(a) the creation of dangerous and harmful metal debris in the patient's body; (b) pain; (c) mobility inhibition; and (d) likelihood of revision surgery with predictable cascading complications." FAC ¶¶ 80, 81; see also FAC ¶ 87. The FAC alleges that the Zimmer failed to warn *inter alia* Crawford's physicians of these dangers. See id. at ¶ 87. Further, the FAC alleges that Zimmer knew or should have known that the use of metals and cobalt-chromium materials in its Hip System created an unreasonable risk of corrosion, micromotion, and fretting, and resulting metallic debris. See id. at ¶¶ 26-36, 41-42, 45. Finally, the FAC alleges that if Zimmer had included proper warnings, no health care professionals, including Crawford's physicians, would have used the Hip System. See id. at ¶ 88.

[2] For example, the FAC contains allegations about what consumers or Crawford would have done if provided with "adequate warnings." However, Zimmer's duty to warn did not run to the general public or to Crawford, it ran only to Crawford's physicians. See Bigler-Engler, 7 Cal.App.5t h at 319; Valentine, 68 Cal.App.4th at 1483.

From the above, the Court reads the second cause of action as alleging that Zimmer provided no warnings to physicians, including Crawford's physician, about the danger of corrosion, fretting and wear from the Hip System's metal components, which could lead to micro metallic debris being released into the body and creating significant complications, even though Zimmer was aware that this was a substantial risk. And, had Crawford's physician been adequately informed of this risk, her physician would not have chosen to implant the Hip System into Crawford's body. So reading the FAC, a plausible claim is stated.[3] See Marroquin, 367 F.Supp.3d at 1161; Andren, 207 F.Supp.3d at 1144.

Zimmer argues in part that the FAC is "cribbed"/largely copied from a federal case that was filed in the Middle District of North Carolina. Zimmer contends that because the FAC is cribbed, the FAC's allegations do not actually relate to the medical devices that were implanted in Crawford. Crawford does not directly address these assertions.

Admittedly, the Court is troubled by the assertion that the FAC's allegations do not actually pertain to the medical implants that were used on Crawford. However, the warning defect that is plausibly alleged is a warning that the metal components had a substantial tendency to fret/rub against each other and corrode, thereby causing micro metallic debris and cascading complications. There is nothing about the allegations in the FAC that obviously demonstrate (at least from a lay perspective) that this defect is inapplicable to the Hip System that was implanted in Crawford. There are no pictures that compare the Hip System (or its components) with the product that is the averred subject of the cribbed North Carolina complaint, nor is there any information from a doctor or knowledgeable Zimmer representative that shows that the defect alleged in the FAC does not or could not apply to the Hip System implanted in Crawford. Simply because different systems manufactured by different corporations are involved does not mean that the same defect could not be present in both implant systems. Moreover, even if such evidence was presented by Zimmer, the Court could not consider such evidence without converting this Rule 12(b)(6) motion into a Rule 56 motion for summary judgment. See Fed. R. Civ. P. 12(b);

[3] To the extent that Crawford intends to allege an additional basis for a strict liability failure to warn claim, the Court finds no other plausible claims under the second cause of action.

Bonilla v. Oakland Scavenger Co., 697 F.2d 1297, 1301 (9th Cir. 1982). In short, the Court is unable to determine whether the allegations in the FAC cannot apply to the Hip System. At this time, the Court will accept that the defects identified in the FAC actually apply to the Hip System implanted in Crawford. See Benavidez, 993 F.3d at 1144 (factual allegations in a complaint are accepted as true when evaluating a Rule 12(b)(6) motion). However, if it is determined through other procedural mechanisms that the FAC's allegations actually do not pertain to the Hip System implanted in Crawford, then Rule 11 clearly would be implicated. For now, the Court holds that a plausible strict liability failure to warn claim has been pled and that dismissal of the entire second cause of action is inappropriate.

3. Third Cause of Action – Strict Liability – Manufacturing Defect

A drug or medical implant manufacturer may be held strictly liable for a manufacturing defect in its product. See Brown v. Superior Ct., 44 Cal.3d 1049, 1069 n.12 (1988); Trejo v. Johnson & Johnson, 13 Cal.App.5th 110, 144 (2017); Garrett, 214 Cal.App.4th at 183. Generally, a "manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." Barker v. Lull Engineering Co, 20 Cal.3d 413, 429 (1978); In re Coordinated Latex Glove Litigation, 99 Cal. App. 4th 594, 605 (2002). The "manufacturing defect" theory posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design." In re Coordinated Latex, 99 Cal.App.4th at 613. That is, "the product does not conform to the manufacturer's design." Garrett, 214 Cal.App.4th at 190. A plaintiff pursuing a manufacturing defect claim must *inter alia* identify/explain how the product either deviated from the manufacturer's intended result/design or how the product deviated from other seemingly identical models; a bare allegation that the product had "a manufacturing defect" is an insufficient legal conclusion. Zetz, 398 F.Supp.3d at 708; Marroquin, 367 F.Supp.3d at 1160; Lucas v. City of Visalia, 726 F.Supp.2d 1149, 1155 (E.D. Cal. 2010); see also Barker, 20 Cal.3d at 429.

Here, the third cause of action fails to explain how the Hip System failed to conform to Zimmer's intended design. Instead, the third cause of action contains two insufficient allegations.

First, the FAC alleges that the design itself rendered the Hip System unreasonably dangerous. See FAC ¶ 104. This allegation pertains to a design defect claim, and, as explained above, California law does not permit a plaintiff to recover on a strict liability design defect theory involving implanted medical devices. See Zetz, 398 F.Supp.3d at 709; Garrett, 214 Cal.App.4th at 184; Artiglio, 22 Cal.App.4th at 1397. Second, the FAC merely repeats a definition of a manufacturing defect: "[the Hip System] deviated in a material way from [Zimmer's] manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula." FAC ¶ 105. Again, the problem is that the FAC does not explain how the Hip System actually differed from Zimmer's design or manufacturing standards. Without an explanation of how the Hip System actually differed, the effect is simply to allege the insufficient legal conclusion that there was a "manufacturing defect." See Zetz, 398 F.Supp.3d at 708; Marroquin, 367 F.Supp.3d at 1160; Lucas, 726 F.Supp.2d at 1155. Because the FAC fails to explain how the Hip System differed from Zimmer's intended design, no plausible claim is stated and dismissal is appropriate.[4] See id.

4. Fourth Cause of Action – Negligence Products Liability

"[U]nder either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused the injury." Merrill v. Navegar, Inc., 26 Cal.4th 465, 479 (2001); Trejo, 13 Cal.App.5th at 125. Under a negligence theory, in addition to proving that a defect caused the injury, the plaintiff must prove the "additional element" that the "defect in the product was due to negligence of the defendant." Merrill, 26 Cal.4th at 479; Trejo, 13 Cal.App.5th at 125; see also Carlin, 13 Cal.4th at 1112 (discussing failure to warn).

Here, the FAC alleges that Zimmer was negligent in its design, warning, and manufacture of the Hip System. That is, the FAC essentially attempts to reallege Crawford's three strict liability claims as negligence claims.

[4] Crawford argues that additional discovery is needed to before she can provide more detailed allegations, including how and why the Hip System failed. However, a plaintiff generally cannot "rely on anticipated discovery to satisfy Rules 8 and 12(b)(6); rather, pleadings must assert well-pleaded factual allegations to advance to discovery." Whitaker 985 F.3d at 1177; see Mujica, 771 F.3d at 593. Thus, Crawford's anticipated discovery is insufficient to prevent dismissal of her strict liability manufacturing defect claim.

With respect to the negligent manufacturing claim, no claim is stated for the same reasons that a strict liability manufacturing is not stated – the FAC fails to identify how the Hip System differed from Zimmer's intended design or from others in the manufacturing batch. See Hannan v. Boston Scientific Corp., 2020 U.S. Dist. LEXIS 79056, *25 (N.D. Cal. May 5, 2020); Zetz, 398 F.Supp.3d at 709; Marroquin, 367 F.Supp.3d at 1164. Therefore, no plausible negligent manufacturing claim is stated. See id.

With respect to the negligent failure to warn claim, as discussed above, a plausible claim under a strict liability theory is pled. The FAC alleges that the defects involved were known or reasonably knowable to Zimmer, yet Zimmer unreasonably failed to include any warnings. The Court is satisfied that a negligent failure warn claim has been plausibly alleged.

With respect to the negligent design defect claim, the Court reads the FAC as alleging that the Hip System is defectively designed because of its use of dissimilar metals and propensity to have metal corrosion and fretting, resulting in the release of micro metallic debris and associated and cascading complications, including metallosis and system failure. The FAC indicates the use of some ceramic components is preferable, and that Zimmer was aware of the dangers in its system, yet Zimmer failed to adequately take steps to mitigate or eliminate these risks in the design and failed to exercise reasonable care in the Hip System's design. The FAC also alleges that the Hip System released micro metallic debris into Crawford's body, which caused pseudotumors, pain, metallosis, and system failure. From these allegations, the Court is satisfied that the FAC contains a plausible negligent design defect claim.

5. Fifth Cause of Action – Negligent Misrepresentation

Crawford argues that she does not need to meet Rule 9(b)'s heightened pleading standard because the claim is based on negligence, not fraud. However, the Ninth Circuit has held that all claims sounding in fraud or grounded in fraud must meet Rule 9(b)'s heightened pleading requirement. See Kearns v. Ford Motor Co., 567 F.3d 1120, 1125 (9th Cir. 2009). California courts have expressly held that "[c]auses of action for intentional and negligent misrepresentation sound in fraud . . . ." Daniels v. Select Portfolio Serving, Inc., 246 Cal.App.4th 1150, 1166 (2016). Moreover, in an unpublished opinion, the Ninth Circuit has held that claims of negligent

misrepresentation under California law sound in fraud. See Avakian v. Wells Fargo Bank, N.A., 827 F. App'x 765, 766 (9th Cir. 2020). Therefore, contrary to Crawford's arguments, her claim of negligent misrepresentation sounds in fraud and she must meet Rule 9(b) heightened pleading standard. See id.; Marroquin, 368 F.Supp.3d at 1166 n.8.

To meet the Rule 9(b) heightened pleading standard, a complaint must identify the who, what, when, where and how of the fraudulent conduct, as well as how and why a statement or conduct is fraudulent. Moore v. Mars Petcare US, Inc., 966 F.3d 1007, 1019 (9th Cir. 2020); Davidson v. Kimberly-Clark Corp., 889 F.3d 956, 964 (9th Cir. 2018). Here, Crawford does not explain how the FAC meets Rule 9(b)'s standards, nor does she expressly argue that she has complied with Rule 9(b). In fact, Crawford's arguments implicitly concedes that the FAC does not meet Rule 9(b)'s standard. Because the fifth cause of action does not comply with Rule 9(b), dismissal is appropriate.

6. Sixth Cause of Action – Breach of Express Warranty

An express warranty is a "contractual promise from the seller that the goods will conform to the promise." Dagher v. Ford Motor Co., 238 Cal.App.4th 905, 928 (2015). A plaintiff is required to allege "the exact terms of the warranty." In re Sony PS3 "Other OS" Litig., 551 Fed. Appx. 916, 919 (9th Cir. 2014) (quoting Williams v. Beechnut Nutrition Corp., 185 Cal.App.3d 135 (1986)); Augustine v. Talking Rain Bev. Co., 386 F.Supp.3d 1317, 1331 (S.D. Cal. 2019); Colgate v. JUUL Labs. Inc., 345 F.Supp.3d 1178, 1195 (N.D. Cal. 2018); Van Lengen v. General Mills. Inc., 185 F.Supp.3d 1213, 1222 (E.D. Cal. 2016). Thus, a plaintiff must allege what "affirmations of fact or promises" relating to the product became a basis for the bargain. See Chambliss v. GMC, 108 F.3d 1176, 1181 (9th Cir. 1997); Houston v. Medtronic, Inc., 957 F.Supp.2d 1166, 1181 (C.D. Cal. 2013). Further, privity of contract is generally a required element of a breach of express warranty claim. See Jones v. Conoco Phillips Co., 198 Cal.App.4h 1187, 1201 (2011); Blanco v. Baxter Healthcare Corp., 158 Cal.App.4th 1039, 1058-59 (2008). However, privity may be excused when there has been reliance on a manufacturer's written representations on a product's labels or advertising. See Fieldstone Co. v. Briggs Plumbing Prods., Inc., 54 Cal.App.4th 357, 369 n.10 (1997). Finally, with respect to implanted medical

devices, the "learned intermediary" rule generally applies. See Hannan, 2020 U.S. Dist. LEXIS 79056 at *29; Hill v. Davol, Inc., 2016 U.S. Dist. LEXIS 188812, *13 (C.D. Cal. Nov. 16, 2016); Tapia v. Davol, Inc., 116 F.Supp.3d 1149, 1162 (S.D. Cal. 2015). Therefore, the physician generally stands in the shoes of the ordinary consumer in terms of expectations regarding the medical device. See Hannan, 2020 U.S. Dist. LEXIS 79056 at *29; Carlin, 13 Cal.4th at 1118. The physician must rely on the express warranty in selecting the medical device. See Lopez v. Johnson & Johnson, 2023 U.S. Dist. LEXIS 19871, *44 (C.D. Cal. Feb. 3, 2023); Tapia, 116 F.Supp.3d at 1162. There can be no liability based on a breach of warranty if a defect in the product that breached the warranty was neither known nor knowable at the time of sale. See Carlin, 13 Cal.4th at 1118.

Here, the FAC can be read as alleging that Zimmer's advertising materials and labels stated that the Hip System was safe and effective at treating conditions like Crawford's. Further, based on the allegations as a whole, the breach of this warranty occurred because of corrosion and fretting, which led to the the release of micro metal debris, and which in turn resulted in implant failure, metallosis, pseudotumors, pain, etc. As this risk was allegedly known to Zimmer or reasonably knowable to Zimmer, a breach of warranty occurred because the Hip System did not adequately treat Crawford's condition and the product was not safe. These allegations all support a plausible breach of express warranty. However, in this case, the learned intermediary rule applies, meaning that the warranty runs to the implanting physician/surgeon.[5] The FAC fails to make any allegations regarding Crawford's physicians/surgeons. Specifically, the FAC fails to allege that Crawford's physicians/surgeons actually relied on the express warranties at issue. Without this reliance, no plausible claim is stated, and dismissal is appropriate. See Lopez, 2023 U.S. Dist. LEXIS 19871 at *44; Tapia, 116 F.Supp.3d at 1162.

7. Seventh Cause of Action – Breach of Implied Warranty

For the implied warranties of merchantability and fitness, privity of contract between the litigants is required. Zetz, 398 F.Supp.3d at 170; Blanco v. Baxter Healthcare Corp., 158

[5] The Court further notes that the FAC alleges that the Zimmer marketed the Hip System to surgeons and hospitals, but not to end-user patients. See FAC ¶ 35.

Cal.App.4th 1039, 1058 (2008). For purposes of implied warranties, privity means that the buyer and seller were parties to the sales contract. See Cardinal Health 301, Inc. v. Tyco Elect. Corp., 169 Cal.App.4th 116, 138 (2008). Subject to various exceptions, there is no privity between the original seller of a product and a subsequent purchaser who is in no way a party to the original sale. Zetz, 398 F.Supp.3d at 710; Cardinal Health, 169 Cal.App.4th at 139; Blanco, 158 Cal.App.4th at 1059. Further, if a patient relies on the skill and judgment of her physician to select a medical implant, then the patient will have no viable implied warranty claims against the manufacturer of the implant. See Blanco, 158 Cal.App.4th at 1058-59.

Here, the FAC alleges that the Hip System was not fit for its ordinary purpose. See FAC ¶ 151. Thus, the FAC is attempting to allege a claim for breach of the implied warranty of merchantability. Cf. Watkins v. MGA Entm't, Inc., 550 F.Supp.3d 815, 832 (N.D. Cal. 2021) (holding that an implied merchantability claim must allege "a fundamental defect that renders the product unfit for its ordinary purpose."). Although the seventh cause of action does not expressly allege why the Hip System is not safe for its ordinary purpose, the other allegations in the FAC indicate that the Hip System is not fit because its metallic components rub together/fret and corrode, thereby releasing micro metallic debris into a patient's body and causing cascading health problems and complications. The FAC also alleges that Crawford's surgeon was "a purchasing agent" who purchased the Hip System for her from Zimmer and thus, Crawford was in privity with Zimmer. See FAC ¶¶ 152, 153. The Court does not find these allegations to be sufficient to satisfy privity.

As stated, the basis for the allegation that Crawford was in privity with Zimmer is that her surgeon was her purchasing agent. See id. However, considering the training, oversight, and nature of the services performed by a surgeon, it does not seem likely that the surgeon agreed to be Crawford's purchasing agent. There are no allegations that the surgeon received or followed any instructions from Crawford with respect to the Hip System. Instead, the allegations indicate that the surgeon selected and purchased the device. That is, the allegation shows that the surgeon used his own judgment and obtained the Hip System, thereby making an implied warranty claim unviable. See Blanco, 158 Cal.App.4th at 1058-59. Moreover, if, as is the normal course of

medical proceedings, the surgeon selected the medical device based on his own skill and judgment, classifying that decision as one by an agent (the surgeon) on behalf of his principal (the patient) would mean that the requirement of privity would always be met in the medical implant context. However, privity is often found to be lacking in such cases. See, e.g., Alvarez v. Bayer US, Inc., 2021 U.S. Dist. LEXIS 258762, *12-*13 (C.D. Cal. Dec. 15, 2021); Zetz, 398 F.Supp.3d at 710 (citing cases). Crediting the allegations as they currently stand would essentially create a new exception to the privity requirement, and it is not the role of a federal district court to create new privity exceptions. See Clemens v. DiamlerChrysler Corp., 534 F.3d 1017, 1024 (9th Cir. 2008); Quatela v. Stryker Corp., 820 F.Supp.2d 1045, 1047 (N.D. Cal. 2010). Therefore, the FAC fails to plausibly meet the privity requirement and thus, an implied warranty of merchantability claim. See Zetz, 398 F.Supp.3d at 710-11; Blanco, 158 Cal.App.4th at 1058-59.

Crawford's opposition cites *Gottsdanker v. Cutter Labs.*, 182 Cal.App.2d 602, 608 (1960) for the proposition that privity is not required for pharmaceutical products. *Gottsdanker* is good law and privity is excused for drugs/pharmaceutical products. See Davis v. Abbott Labs, 562 F.Supp.3d 585, 588 (C.D. Cal. 2021); Chavez v. Glock, Inc., 207 Cal.App.4th 1283, 1315 (2012). Nevertheless, the product at issue in this case is not a drug/pharmaceutical product; it is an implanted medical device. *Gottsdanker* has not been extended to cover implanted medical devices. See Tapia, 116 F.Supp.3d at 1159-60; Quatela, 820 F.Supp.2d at 1047. Thus, privity remains a requirement for implied warranty claims involving implanted medical devices. See Zetz, 398 F.Supp.3d at 710; Tapia, 116 F.Supp.3d at 1159-60; Quatela, 820 F.Supp.2d at 1047; Blanco, 158 Cal.App.4th at 1058-59; Evraets v. Intermedics Intraocular, Inc., 29 Cal.App.4th 779, 788 (1994).

8. Leave to Amend

The Court has found that the FAC alleges plausible claims for strict liability failure to warn, negligent design defect, and negligent failure to warn. No other plausible claims are alleged. With respect to the strict liability manufacturing defect, negligent manufacturing defect, negligent misrepresentation, and breach of express warranty claims, the Court cannot determine whether granting leave to amend would be futile. Therefore, these claims will be dismissed with

leave to amend. However, with respect to the strict liability design defect and implied warranty claims, amendment appears futile. The law is well established that no strict liability design defect can be alleged against a manufacturer, and, due to an absence of privity, no implied warranty claim can be stated when a patient relies on the physician/surgeon to select an implanted medical device. Therefore, the strict liability design defect and breach of implied warranty claims will be dismissed without leave to amend.

9. Motion to Strike

A Rule 12(f) motion to strike may be granted with respect to "immaterial matter." See Fed. R. Civ. P. 12(f); Whittlestone, Inc. v. Handi-Craft Co., 618 F.3d 970, 974 (9th Cir. 2010). "Immaterial matters" are allegations that "do not pertain, and are not necessary, to the issues in question." Id. Motions to strike are generally disfavored. Hawkins v. Medtronic, Inc., 62 F.Supp.3d 1144, 1149 (E.D. Cal. 2014).

Here, as discussed above, there is insufficient information before the Court to definitively determine whether the FAC's allegations accurately reflect the true facts and circumstances of this case or whether they reflect only the facts in the Middle District of North Carolina matter. Until additional information is presented through the appropriate procedural mechanism, the Court will follow the Rule 12(b)(6) presumptions and also presume that Crawford's counsel has followed the requirements of Rule 11. With these presumptions, the Court cannot hold that the FAC's allegations are immaterial. Therefore, Zimmer's Rule 12(f) motion will be denied without prejudice.

ORDER

Accordingly, IT IS HEREBY ORDERED that:

1. Defendants' motion to dismiss (Doc. No. 34) is DENIED with respect to Crawford's strict liability failure to warn, negligent design defect, and negligent failure to warn claims;
2. Defendants' motion to dismiss is GRANTED with respect to all other claims;
3. Crawford's strict liability design defect and breach of implied warranty claims are DISMISSED without leave to amend;

4. Crawford's strict liability manufacturing defect, negligent manufacturing defect, negligent misrepresentation, and breach of express warranty claims are DISMISSED with leave to amend;

5. Defendants' motion to strike (Doc. No. 34) is DENIED;

6. No later than twenty-one (21) days of service of this order, Crawford may file an amended complaint that is consistent with the analysis of this order and Rule 11;

7. If Crawford fails to file a timely amended complaint, then leave to amend shall be deemed to be automatically withdrawn and Defendants shall file an answer within twenty-eight (28) days of service of this order.

IT IS SO ORDERED.

Dated: February 23, 2023

SENIOR DISTRICT JUDGE